

CLAIMS

1. A composition comprising a purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids or ester form thereof or synthetic form thereof and a pharmaceutically acceptable carrier or adjuvant, wherein the pharmaceutically acceptable carrier is suitable for direct administration to the lungs of a subject.
2. A composition according to claim 1, wherein the purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids is from *Mycobacterium tuberculosis*.
3. - A composition according to claim 1, wherein the pharmaceutically acceptable carrier is a vaporisable liquid.
4. A composition according to claim 3, wherein the vaporisable liquid is a saline solution.
5. A composition comprising a purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids or ester form thereof or synthetic form thereof and a pharmaceutically acceptable carrier or adjuvant, wherein the composition comprises a tolerogenic amount of the purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids or ester form thereof or synthetic form thereof.
6. A composition according to claim 5, wherein the purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids is from *Mycobacterium tuberculosis*.
7. A prophylactic pharmaceutical composition for an immune disorder, comprising a purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids or ester form thereof or synthetic form thereof and a pharmaceutically acceptable carrier or adjuvant.

8. A vaccine according to claim 7, wherein the immune disorder is arthritis.
9. A method of decreasing the pathogenic effects of a mycobacterial infection in the lungs of a subject by administering to the subject a purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids or ester form thereof or synthetic form thereof to stimulate the innate immunity of the subject.
10. A method according to claim 9, which is a prophylactic method or a therapeutic method.
11. A method according to claim 10, which is an immunoregulatory method.
12. A method according to claim 10 or 11, which is a prophylactic method which enhances resistance or reduces susceptibility to a micobacterial infection in a subject.
13. A method according to claim 12, wherein the prophylactic method promotes a pro-inflammatory response in the lungs of the subject.
14. A method according to claim 10 or 11, wherein the prophylactic method or the therapeutic method modulates or manipulates the humoral immune system or cellular immune system or both in a subject.
15. A method according to claim 12 or 13, wherein the prophylactic method stimulates the expression of IL12 IFN- $\gamma$  in the lungs of the subject.
16. A method according to claim 10, wherein the therapeutic method stimulates the expression of TGF- $\beta$  in the lungs of the subject.
17. A method according to claim 10, wherein the mycobacterial infection is tuberculosis.

18. A purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids or ester form thereof or synthetic form thereof for use in a method of decreasing the pathogenic effects of a mycobacterial infection in the lungs of a subject by stimulating the innate immunity of the subject.
19. Use of a purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids or ester form thereof or synthetic form thereof in a method of making a medicament for use in a method of decreasing the pathogenic effects of a mycobacterial infection in the lungs of a subject by stimulating the innate immunity of the subject.
20. A purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids according to claim 18 or 19, wherein the method of treatment is a prophylactic method or a therapeutic method.
21. A purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids according to claim 20, wherein the method of treatment is an immunoregulatory method.
22. A purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids or ester form thereof or synthetic form thereof according to claim 18 or 19, wherein the method of treatment is a prophylactic method which enhances resistance or reduces susceptibility to a mycobacterial infection in a subject.
23. A purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids according to claim 22, wherein the prophylactic method promotes a pro-inflammatory response in the lungs of the subject.
24. A purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids according to claim 20 or 21, wherein the prophylactic method or the therapeutic method modulates or manipulates the humoral immune system or cellular immune system or both in a subject.

25. A purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids according to claim 22, wherein the mycobacterial infection is tuberculosis.
26. A purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids according to claim 20, wherein the method of treatment is a prophylactic method which stimulates the expression of IL12 and IFN- $\gamma$  in the lungs of the subject.
27. A purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids according to claim 20, wherein the method of treatment is a therapeutic method which stimulates the expression of TGF- $\beta$  in the lungs of the subject.
28. A method of diagnosing an immune disorder in a subject comprising the steps of:  
contacting a sample from the subject with a purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids or ester form thereof or synthetic form thereof; and  
detecting any immunological reaction between the purified mycobacterial mycolic acid or mixture of purified mycolic acids and the sample.
29. A method according to claim 28, wherein the step of detecting any reaction between the purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids or ester form thereof or synthetic form thereof and the sample comprises detecting the binding of an antibody present in the sample to the purified mycobacterial mycolic acid component.
30. A method of treatment of an immune disorder in a subject comprising the step of administering to the subject a purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids or ester form thereof or synthetic form thereof.

31. A method according to claim 30, which is a prophylactic method or a therapeutic method.
32. A method according to claim 31, which is an immunoregulatory method.
33. A method according to claim 31 or 32, which is a prophylactic method which enhances resistance or reduces susceptibility to an immune disorder in a subject.
34. A method according to claim 33, wherein the prophylactic method suppresses inflammation of the joints in the subject.
35. A method according to claim 31 or 32, wherein the prophylactic method or the therapeutic method modulates or manipulates the humoral immune system or cellular immune system or both in a subject.
36. A method according to any one of claims 30 to 35, wherein the immune disorder is an inflammatory condition or allergy.
37. A method according to claim 36, wherein the inflammatory condition is an autoimmune disease.
38. A method according to claim 37, wherein the autoimmune disease is arthritis.
39. A purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids or ester form thereof or synthetic form thereof for use in a method of treatment of an immune disorder in a subject.
40. Use of a purified mycobacterial mycolic acid or mixture of purified mycobacterial mycolic acids or ester form thereof or synthetic form thereof in a method of making a medicament for use in the treatment of an immune disorder in a subject.

41. A purified mycobacterial mycolic acid, mixture, ester or synthetic form according to claim 39 or 40, wherein the method of treatment is a prophylactic method or a therapeutic method.
42. A purified mycobacterial mycolic acid, mixture, ester or synthetic form according to claim 41, wherein the method of treatment is an immunoregulatory method.
43. A purified mycobacterial mycolic acid, mixture, ester or synthetic form according to claim 41 or 42, wherein the method of treatment is a prophylactic method which enhances resistance or reduces susceptibility to an immune disorder in a subject.
44. A purified mycobacterial mycolic acid, mixture, ester or synthetic form according to claim 43, wherein the prophylactic method suppresses inflammation of the joints in the subject.
45. A purified mycobacterial mycolic acid, mixture, ester or synthetic form according to claim 41 or 42, wherein the prophylactic method or the therapeutic method modulates or manipulates the humoral immune system or cellular immune system or both in a subject.
46. A purified mycobacterial mycolic acid, mixture, ester or synthetic form according to any one of claims 39 to 45, wherein the immune disorder is an inflammatory condition or allergy.
47. A purified mycobacterial mycolic acid, mixture, ester or synthetic form according to claim 46, wherein the inflammatory condition is an autoimmune disease.
48. A purified mycobacterial mycolic acid, mixture, ester or synthetic form according to claim 47, wherein the autoimmune disease is arthritis.

49. A method of separating and purifying a specific microbial cell-wall component of a lipid or carbohydrate nature or a derivative or analog thereof from an extracted mixture of the cell-wall component or derivative or analog thereof and contaminants or from a synthetic mixture of the cell-wall component or derivative or analog thereof and contaminants, comprising the steps of:
- dissolving the extracted mixture or synthetic mixture in a bi-phasic solvent containing sodium chloride to form a solution;
  - allowing the solution to separate to form an upper phase and a lower phase;
  - subjecting the phases to countercurrent distribution/separation comprising a required number of cycles to separate the microbial cell-wall component or analog or derivative thereof in the upper phase or the lower phase; and
  - removing the separated microbial cell-wall component or derivative or analog thereof from the upper or lower phase.
50. A method according to claim 49, which also comprises the additional pre-purification steps of:
- dissolving the extracted mixture of cell-wall component or derivative or analog thereof and contaminants or the synthetic mixture of the cell-wall component or derivative or analog thereof and contaminants in a first solvent without sodium chloride;
  - adding thereto a second solvent without sodium chloride;
  - mixing and allowing the solution to separate to form a first upper phase (second solvent) and first lower phase (first solvent); and
  - removing the first upper phase and/or the first lower phase for further processing.
51. A method according to claim 49 or 50, wherein the lower phase containing the extracted mixture is removed and subjected to countercurrent distribution/separation comprising a required number of cycles to separate the microbial cell-wall component or analog or derivative thereof in a second upper phase or lower phase and the separated microbial cell-wall component

or derivative or analog thereof is removed from the second upper or lower phase.

52. A method according to any one of claims 49 to 51, which also comprises the additional post-purification steps of:
- dissolving the extracted microbial cell-wall component or derivative or analog thereof in a suitable solvent; and
  - adding a precipitant to the solution to precipitate out the dissolved further purified microbial cell-wall component or derivative or analog thereof.
53. A method according to claim 52, wherein the solvent is chloroform.
54. A method according to claim 52 or 53, wherein the precipitant is acetone.
55. A method according to any one of claims 49 to 54, which also comprises the steps of:
- saponifying a microbial culture prior to preparing therefrom an extracted mixture of a cell-wall component or derivative or analog thereof on which to perform the method; and
  - resaponifying the separate and purified microbial cell-wall component or derivative or analog thereof.
56. Detection means for detecting the presence of antibodies to a purified mycolic acid or mixture of purified mycolic acids comprising a solid phase and an unconjugated purified mycolic acid or a mixture of unconjugated purified mycolic acids in a methylester form or in a freshly resaponified form associated therewith.
57. Detection means according to claim 56, wherein the solid phase is an ELISA plate.
58. A prophylactic pharmaceutical composition according to claim 7, wherein the immune disorder is an autoimmune disorder.

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